MAY - 3 2000

510(k) Summary

K000380

This 510(k) summary is being submitted in accordance with the requirements of 21 CFR 807.92.

(A)(1) Submitter's name: Hamilton Thorne Research
Submitter's address: 100 Cummings Center, Suite 102-C
Beverly, MA 01915
Submitter's telephone no.: 978 -921-2050
Contact Person: Diarmaid Douglas-Hamilton
Date Summary Prepared: February 4, 2000

(2) Trade or proprietary device name: FotoMaster™
Common or usual name: Picture archiving and communications system (PACS)
Classification name: Picture archiving and communications system (PACS)
21 CFR 892.2050
Panel: Radiology

(3) Legally marketed predicate device: DIMS (Digital Imaging and Medical System)
[DenVu L.C., K970813, SE 5/8/97]

(4) Subject device description:

The FotoMaster™ is a personal computer-based software system which takes photographs from live videos from endoscopy and captures these pictures in archives for retrieval, report generation, or transfer to secondary data communications systems.

The FotoMaster™ operates by preconnection to standard video equipment and camera in the operating theater or examination room. The FotoMaster™ is designed to work with existing equipment and contains a capture PC with video capture board, VGA monitor, keyboard and mouse, remote control trigger and printer. The patient is registered into the system which creates files for storage of the recorded images. Patient data is stored according to diagnosis and easily retrievable by key words or date. Up to 10,000 patient files can be stored on hard disc.

(5) Subject device intended use:

The FotoMaster™ is a picture archiving and communications system (PACS), which takes photographs from live videos from endoscopy and captures these pictures in archives for retrieval, report generation, or transfer to secondary data communications systems.

(6) Technological characteristics:

The FotoMaster™ can display, process, annotate, digitize, store and retrieve images obtained during endoscopy using remote control trigger, and support hardware and software components. It uses the standard publicly available JPEG image compression algorithms from the independent JPEG Group's Software Library.

(7) Performance testing:

Comparison testing to predicate was not provided for this 510 (k).

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAY - 3 2000

Diarmaid Douglas-Hamilton
VP of Research and Development
Hamilton Thorne Research
100 Cummings Center
Suite 102-C
Beverly, MA 01915

Re: K000380
FotoMaster™ PACS Device
Dated: February 4, 2000
Received: February 7, 2000
Regulatory class: II
21 CFR 892.2050/Procode: 90 LLZ

Dear Ms. Hamilton:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4591. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

Daniel G. Schultz, M.D.
Captain, USPHS
Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure(s)

C. Indications for use of the Device

510(k) Number): ~~Not known~~ K000380

Device Name: FotoMaster™

Indications for Use:

The FotoMaster™ is a picture archiving and communications system (PACS) which takes photographs from live videos from endoscopy and captures these pictures in archives for retrieval, report generation, or transfer to secondary data communications systems.

(Please do not write below this line—continue on another page if needed)

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use X **Or Over-the-Counter Use**
(Per 21 CFR 801.109) (Optional Format 1-2-96)

(Division Sign-Off)
Division of Reproductive, Abdominal, ENT,
and Radiological Devices
510(k) Number K000380